K121152

Section 5: 510(k) Summary

1. **Preparation Date:** April 12, 2012

DEC 12 2012

2. **Submitted by:**

Jiangsu Guangda Medical Material Co., Ltd.
18 BaoChang Road North, LiBao Town,
Haian County, Jiangsu Province, China 226631
Owner/Operator #: 10023676
Registration Number: 3006847952

3. **Contact Person/Prepared by:**

Darren Reeves
Phone: (804) 307-7706
Fax: (866) 393-4954
Email: dreeves@dpdconline.com

4. **Device Identification:**

Trade Name: Surgical Gown
Common Name: Gown, Surgical
Classification: Surgical Apparel, FYA, Class 2 (878.4040)

5. **Predicate Device:** GRI MEDICAL Surgical Gowns (K102652)

6. **Device Description:**

Jiangsu Guangda's Disposable XLarge Reinforced Surgical Gowns, Model Number GD-SG-01, are made from SMS fabrics and PE + PP two layer compound protective reinforcement with 100% white Terylene cuffs to provide user protection in surgical settings.

7. **Intended Use:**

Jiangsu Guangda's Reinforced Surgical Gowns, Model Number GD-SG-01, are non-sterile, single use surgical gowns intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material.
This product may be sterilized using Ethylene Oxide (EO) following the validation and routine control under ANSI/AAMI/ISO 11135.

8. Comparison to Predicate:

The following table shows similarities and differences between the predicate identified in Section 5 of this summary. There are no significant differences between the Jiangsu Guangda's Gowns, Model Number GD-SG-01, and their respective predicate products.

Item		**Proposed Device:** Jiangsu Guangda's Gowns, Model Number GD-SG-01	**Predicate Device:** GRI MEDICAL Surgical Gowns (K102652)
Product Code		FYA, Class II	FYA, Class II
Intended Use		Jiangsu Guangda's Reinforced Surgical Gowns are non-sterile, single use surgical gowns intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. This product may be sterilized using Ethylene Oxide (EO) following the validation and routine control under ANSI/AAMI/ISO 11135.	GRI's Non Reinforced, Film Reinforced, and Fabric Reinforced Surgical Gowns are sterile and non-sterile, single use surgical gowns intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material.
Style		Reinforced	Reinforced and non-reinforced
Durability		Disposable	Disposable
Size		XL	Various
Color		Blue	Various
Material		SMS and PE+PP two layer compound	Same
Weight per square		45 g/m^2	50 g/m^2
Label and Labeling		Conforms to FDA Requirements	Unknown
Liquid Barrier Performance: ANSI/AAMI PB70	Hydrostatic Pressure: AATCC Test Method 127	All were >20	Has met acceptance criteria
	Impact Penetration: AATCC Test Method 42	All were ≤1	Has met acceptance criteria
	Resistance by Blood-Borne Pathogen: ASTM- F1671	All were ≤1	Unknown
	Resistance by Synthetic Blood: ASTM- F1670	Passed	Has met acceptance criteria
Physical Specifications	Breaking Strength: ASTM-D5034	Passed	Has met acceptance criteria
	Tearing Strength: ASTM– D5733	Passed	Has met acceptance criteria
	Flammability Test Method (16 CFR 1610)	Class I	Has met acceptance criteria
	Seam Strength: ASTM– D1683	Passed	Has met acceptance criteria
Biocompatibility: ISO 10993-1	Cytotoxicity: ISO 10993-5	Passed	Has met acceptance criteria
	Irritation: ISO 10993-10	Passed	Has met acceptance criteria
	Sensitization: ISO 10993-10	Passed	Has met acceptance criteria
Sterilization	Method	Although sold non-sterile, gowns can be EO Sterilized	Unknown
	EO and ECH Residual	Conforms to ISO 10993-7	Unknown

9. Summary of Testing:

The information in the Premarket Notification on safety and efficiency supports a finding of substantially equivalence to devices already in commercial distribution. Equivalence is demonstrated through intended use, material, design and testing methods.

Test Data Provided in this Submission

Standard or Guidance	Data Generated	Relevant Section of Submission
ASTM- F2407-06 Standard Specification for Surgical Gowns intended for Use in Healthcare Facilities		
AAMI/ANSI/ISO 10993-1:2003(E), Biological evaluation of medical devices -- Part 1: Evaluation and testing	Biocompatibility Testing Evaluation	15
AAMI/ANSI/ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity	Cytotoxicity	15
AAMI/ANSI/ISO 10993-10:2010, Biological evaluation of medical devices -- Part 10: Tests for irritation and sensitization	Skin Irritation, intra-cutaneous reactivity & sensitization	15
ANSI/AAMI PB70:2003, Liquid Barrier Performance and Classification of protective apparel and drapes intended for use in health care facilities	Barrier Performance	18
AATCC Test Method 127-2007&2008 Hydrostatic Pressure: Option 2	Water Resistance	18
AATCC Test Method 42-2007 Impact Penetration: Type II	Water Resistance	18
ASTM- F1671:2007 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens	Resistance to Penetration	18
ASTM- F1670:2008 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood	Resistance to Penetration	18
ASTM- D5034:1995 Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)	Tensile Strength	18
ASTM– D5733:1999 Standard Test Method for Tearing Strength of Nonwoven Fabrics by Trapezoid Procedure	Tearing Strength	18
ASTM– D1683:2007 Standard Test Method for Failure in Sewn Seams of Woven Apparel Fabrics	Seam Strength Test	18
CPSC CS-191-53 Flammability Test Method (16 CFR 1610) Standard for Flammability of Clothing Textiles	Flammability	18

The predicate, GRI MEDICAL Surgical Gowns (K102652) met acceptance criteria for bench testing including biocompatibility, hydrostatic pressure, impact penetration, Resistance to Penetration by Synthetic Blood, flammability, and strength via tensile, tear and seam strength.

10. Conclusion:

The information in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to devices already in commercial distribution. Equivalence is demonstrated through intended use, materials, design and testing methods.

11. Similarities/Differences of the proposed device when compared to the predicate:

The data within this submission demonstrates that there are no significant differences between the application device and the predicate, indicating that the application device is safe, effective and substantially equivalent for marketing in the U.S.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 12, 2012

Mr. Darren Reeves
Jiangsu Guangda Medical Material Company, Limited
7305 Hancock Village Drive, Suite 109
CHESTERFIELD VA 23832

Re: K121152
Trade/Device Name: Jiangsu Guangda Surgical Gown, Model Number GD-SG-01
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FYA
Dated: November 30, 2012
Received: December 4, 2012

Dear Mr. Reeves:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

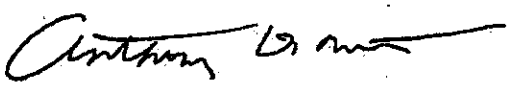
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.A., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

FDA U.S. Food and Drug Administration

Department of Health and Human Services

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

K121152

Indications for Use

510(k) Number (if known): K121152

Device Name: Jiangsu Guangda Surgical Gown, Model Number GD-SG-01

Indications for Use:

Jiangsu Guangda's Reinforced Surgical Gowns are non-sterile, single use surgical gowns intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material.

This product may be sterilized using Ethylene Oxide (EO) following the validation and routine control under ANSI/AAMI/ISO 11135.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie
2012.12.11 18:08:11 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K121152